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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,316	08/20/2001	Stephen C Porter	29985/01-185	7064

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/933,316

Applicant(s)

PORTER, STEPHEN C

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,9-11 and 15-41 is/are pending in the application.
- 4a) Of the above claim(s) 29-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,9-11,15-28 and 38-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 1, 2004 has been entered.

Claims 1, 3-5, 9-11, 15-41 are pending. Claims 1, 3-5, 9-11, 15-28, 38-41 read on the elected species and are under consideration. Claims 29-37 are withdrawn from further consideration for the reasons set forth in Paper Nos. 3, 5-6.

Applicant's arguments filed on October 1, 2004 have been fully considered and are found persuasive in view of the Amendments. Specifically, The rejection of claims 1-5, 7-11, 15-21, 23-26 under 35 U.S.C. 103(a) as being unpatentable over Krall et al WO 00/44287 (WO '87) in view of Evans US Patent 5,702,361 has been withdrawn in view of the claim amendments. However, Examiner points out that Applicant's arguments were only applicable to the use of such non-cyanoacrylate polymeric moiety described in Evans which were limited to cellulose diacetate and/or ethylene vinyl alcohol copolymers. Accordingly, the search has been extended to identify the use of other non-cyanoacrylate polymers such as poly(vinyl esters) or poly(vinylethers) in combination with alkyl cyanoacrylate monomers. Subsequently, the following rejection is applied to the claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-5, 9-11, 15-28, 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krall et al WO 00/44287 (WO '287) in view of Slaikeu et al US Patent 6,160,025.

Krall discloses compositions comprising the two components of M1 and M2 (abstract; example 6, pages 50-53). M1 meets the limitation of the instant matrix-forming material because it contains 2-Hexyl Cyanoacrylate, which is an alkyl cyanoacrylate monomer in amounts of about 49% wt in total formulation. (see page 18, lines 18-20, example 4, page 47). M1 further contains hydroquinone, p-methoxyphenol and phosphoric acid as the stabilizers (page 6, lines 24-33; page 7, lines 1-26; page 19, lines 20-25, page 62, claims 1-9). Krall uses and claims such amounts of hydroquinone

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and phosphoric acid that falls within the ranges of the instant claim 20 (see page 63, lines 11-20). Krall also discloses the use of n-butyl cyanacrylates in amounts of about 33% wt. (see examples 4-5, 7, pages 47-54).

The M2 component of Krall contains a radiopaque moiety, which can be pure gold powder, iodinated oil or other like agents (page 17, lines 1-10; page 26, lines 18-26; page 27, lines 1-25). Krall specifically uses powdered gold, which meets the instant solid aggregate material limitation of claim 1 (page 50, line 15; example 6).

The ethyl myristate and the Ethiodol of Krall also anticipate the plasticizer component of instant claim 1 and 26, because they are respectively an alkyl ester and an iodinated oil and fall within the plasticizers enumerated in the instant claims 25-26. (see page 64, lines 1-6; and page 65, lines 15-18).

Krall's composition only lacks a polymeric non-cyanoacrylate rheology modifying agent that has an average molecular weight greater than 200,000.

Slaikeu is used to show that non-cyanoacrylate polymeric moieties, such as polyvinyl acetate (PVA) having a molecular weight (MW) in the ranges of 10,000-500,000, are suitable polymers for use as embolizing agent (abstract; col 9, lines 19-35). Slaikeu specifically provides that viscosities of polymeric embolizing agents are sensitive to the MW of the polymer employed. (see col 5, lines 1-3). Accordingly, Slaikeu provides guidance that MW can be modified to provide optimal viscosity for the final embolizing agents (see col 5, lines 5-26). Formulation of Slaikeu's like Krall contains a radiopaque material for ease of monitoring the therapeutic outcome (see col 8, example 12).

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It has been held to be *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. In re Kerkhoven, 205 USPQ 1069 (CCPA 1980).

Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to add a suitable polymeric embolic formulation, such as the PVA polymers of Slaikou at molecular weights above 200,000 to optimize the viscosity and flow of the formulation of Krall WO '287, because such a modification would have involved a mere addition of Slaikou's polymeric compositions to those of Krall's and as reasoned in Kerkhoven, the idea of combining them flows logically by the prior art.

Claims 1, 3-5, 9-11, 15-28, 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krall et al WO 00/44287 (WO '287) in view of Slaikou et al US Patent 6,160,025 as applied to claims 1, 3-5, 9-11, 15-28, 39-41 and further in view of Hechenberger et al US Patent 4,997,861.

The teachings of Krall and Slaikou are described above. Their combined teachings do not use an inorganic particulate material such as fumed silica.

Hechenberger teaches polymeric adhesive compositions containing cyanoacrylate and non-cyanoacrylate polymers in combination with fumed silica (abstract; col 4). Hechenberger suggests that use of non-cyanoacrylate polymers and an inorganic thickener such as fumed silica provides improves stability and adhesive

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properties of cyanoacrylate polymeric adhesive agents (see col 2, lines 63-col 3, lines 20).

Accordingly since Hechenberger suggests that addition of fumed silica would improve adhesive properties of cyanoacrylate compositions, it would have been obvious to one of ordinary skill in the art at the time of invention to further add fumed silica to the formulations of Krall and Slaikeu, because the ordinary skill in the art would have had a reasonable expectation of success to enhance the adhesive properties of such compositions.

### ***Conclusion***

No claims are allowed.

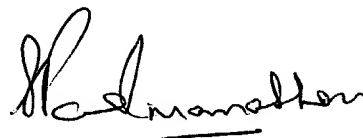
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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**SREENI PADMANABHAN**  
**SUPERVISORY PATENT EXAMINER**